Complete Summary

GUIDELINE TITLE

Clinical policy: procedural sedation and analgesia in the emergency department.

BIBLIOGRAPHIC SOURCE(S)

Godwin SA, Caro DA, Wolf SJ, Jagoda AS, Charles R, Marett BE, Moore J, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med 2005 Feb;45(2):177-96. [72 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Emergency Physicians. Clinical policy for procedural sedation and analgesia in the emergency department. Ann Emerg Med 1998 May;31(5):663-77.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Emergent and urgent conditions that require sedation and/or analgesia to successfully accomplish an interventional or diagnostic procedure in the Emergency Department

GUIDELINE CATEGORY

Evaluation
Management
Risk Assessment

CLINICAL SPECIALTY

Anesthesiology
Cardiology
Emergency Medicine
Gastroenterology
Orthopedic Surgery
Pediatrics
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations for procedural sedation and analgesia in the hospital Emergency Department (ED)
- To address the following critical questions:
    - What are the personnel requirements needed to provide procedural sedation and analgesia in the ED?
    - What are the key components of the patient assessment before initiating procedural sedation?
    - Is preprocedural fasting necessary before initiating procedural sedation?
    - What equipment and supplies are required to provide procedural sedation and analgesia?
    - What assessment and monitoring are required to provide procedural sedation in the ED?
    - How should respiratory status be assessed?
    - Can ketamine, midazolam, fentanyl, propofol, and etomidate be safely administered for procedural sedation and analgesia in the ED?

TARGET POPULATION

- Emergency Department (ED) patients of all ages who have emergent or urgent conditions that require pain and/or anxiety management to successfully accomplish an interventional or diagnostic procedure.
- High-risk patients (e.g., those with underlying cardiopulmonary disorders, multiple trauma, head trauma, or who have ingested a central nervous system depressant such as alcohol) are included with the understanding that these patients are at increased risk of complications from procedural sedation and analgesia.

These guidelines are <u>not</u> intended for use in the following types of patients:

- Patients receiving inhalational anesthetics

- Patients who receive analgesia for pain control without sedatives
- Patients who receive sedation solely for the purpose of managing behavioral emergencies
- Patients who are intubated

INTERVENTIONS AND PRACTICES CONSIDERED

1. Personnel requirements to provide procedural sedation and analgesia in the emergency department
2. Patient assessment prior to procedural sedation including history and physical examination
3. Availability of equipment and supplies, such as oxygen, suction, reversal agents, and advanced life support medications and equipment during the procedural sedation and analgesia
4. Patient assessment and monitoring requirements for procedural sedation and analgesia in the emergency department
5. Pulse oximetry and capnometry if indicated

   Note: The routine use of Bispectral Index was considered but not recommended due to insufficient evidence.

6. Sedation and analgesia in the emergency department with ketamine, midazolam, fentanyl, propofol, and etomidate

MAJOR OUTCOMES CONSIDERED

- Patient safety considerations for procedural sedation and analgesia in the emergency department
- Safety and efficacy of a variety of agents for procedural sedation and analgesia in the emergency department

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A MEDLINE search of English-language articles published between January 1992 and January 2004 was performed using combinations of the key words "conscious sedation," "moderate sedation," "deep sedation," "analgesia," "sedation," "standards," "guidelines," "complications," and "emergency department." Terms were then exploded as appropriate. Abstracts and articles were reviewed by subcommittee members, and pertinent articles were selected. These articles were evaluated, and those addressing the questions considered in this document were chosen for grading. Subcommittee members also supplied references from bibliographies of initially selected articles or from their own files.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence

Class I - Interventional studies including clinical trials, observational studies including prospective cohort studies, and aggregate studies including meta-analyses of randomized clinical trials only

Class II - Observational studies including retrospective cohort studies, case-controlled studies, and aggregate studies including other meta-analyses

Class III - Descriptive cross-sectional studies, observational reports including case series and case reports, and consensus studies including published panel consensus by acknowledged groups of experts.

Strength of evidence Class I and II articles were rated on elements the committee believed were most important in creating a quality work. Class I and II articles with significant flaws or design bias were downgraded on the basis of a set formula (see Appendix B in the original guideline document). Strength of evidence Class III articles were downgraded if they demonstrated significant flaws or bias. Articles down-graded below a Class III strength of evidence were given an "X" rating and were not used in formulating recommendations in this policy.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

All publications were graded by at least 2 of the subcommittee members into 1 of 3 categories of strength of evidence. Some articles were downgraded on the basis of a standardized formula that considers the size of study population, methodology, validity of conclusions, and potential sources of bias.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

This policy is a product of the American College of Emergency Physicians (ACEP) clinical policy development process and is based on the existing literature; where literature was not available, consensus of emergency physicians was used.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations regarding patient management were made according to the following criteria:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all the issues)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Expert review comments were received from emergency physicians, individual members of American College of Emergency Physician's (ACEP's) Pediatric Emergency Medicine Committee and Section, and individual members of the American Society of Anesthesiologists. Their responses were used to further refine and enhance this policy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Class I-III) and strength of recommendations (A-C) are repeated at the end of the "Major Recommendations" field.

What are the personnel requirements needed to provide procedural sedation and analgesia in the ED?

- Level A recommendations. None specified.
- Level B recommendations. None specified.
- Level C recommendations. During moderate and deep sedation, a qualified support person should be present for continuous monitoring of the patient.

  Procedural sedation and analgesia in the Emergency Department (ED) must be supervised by an emergency physician or other appropriately trained and credentialed specialist.

What are the key components of the patient assessment before initiating procedural sedation?

- Level A recommendations. None specified.
- Level B recommendations. None specified.
- Level C recommendations. Obtain a history and perform a physical examination to identify medical illnesses, medications, allergies, and anatomic features that may affect procedural sedation and analgesia and airway management.

  No routine diagnostic testing is required before procedural sedation.

Is preprocedural fasting necessary before initiating procedural sedation?

- Level A recommendations. None specified.
- Level B recommendations. None specified.
- Level C recommendations. Recent food intake is not a contraindication for administering procedural sedation and analgesia, but should be considered in choosing the timing and target level of sedation.

What equipment and supplies are required to provide procedural sedation and analgesia?

- Level A recommendations. None specified.
- Level B recommendations. None specified.
- Level C recommendations. Oxygen, suction, reversal agents, and advanced life support medications and equipment should be available when procedural sedation and analgesia is used.

Intravenous access should be maintained when intravenous procedural sedation and analgesia is provided. Intravenous access may not be necessary when procedural sedation and analgesia is provided by other routes.

What assessment and monitoring are required to provide procedural sedation in the ED?

- Level A recommendations. None specified.
- Level B recommendations. None specified.
- Level C recommendations. Obtain and document vital signs before, during, and after procedural sedation and analgesia. Monitor the patient's appearance and ability to respond to verbal stimuli during and after procedural sedation and analgesia.

How should respiratory status be assessed?

- Level A recommendations. None specified.
- Level B recommendations. Pulse oximetry should be used in patients at increased risk of developing hypoxemia, such as when high doses of drugs or multiple drugs are used, or when treating patients with significant comorbidity.
- Level C recommendations. When the patient's level of consciousness is minimally depressed and verbal communication can be continually monitored, pulse oximetry may not be necessary.

  Consider capnometry to provide additional information regarding early identification of hypoventilation.

Can ketamine, midazolam, fentanyl, propofol, and etomidate be safely administered for procedural sedation and analgesia in the ED?

- Level A recommendations. Ketamine can be safely administered to children for procedural sedation and analgesia in the ED.
- Level B recommendations. Propofol can be safely administered for procedural sedation and analgesia in the ED.

  Nondissociative sedation agents should be titrated to clinical effect to maximize safety during procedural sedation in the ED.

  The combination of fentanyl and midazolam is effective for procedural sedation and analgesia in the ED.

- Level C recommendations. Etomidate can be safely administered for procedural sedation and analgesia in the ED.

Definitions:

Strength of Evidence

Class I - Interventional studies including clinical trials, observational studies including prospective cohort studies, and aggregate studies including meta-analyses of randomized clinical trials only

Class II - Observational studies including retrospective cohort studies, case-controlled studies, and aggregate studies including other meta-analyses

Class III - Descriptive cross-sectional studies, observational reports including case series and case reports, and consensus studies including published panel consensus by acknowledged groups of experts

Strength of Recommendation

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all the issues)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations. Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Safe and effective procedural sedation and analgesia in the hospital Emergency Department
- Proactively addressing pain and anxiety may improve quality of care and patient satisfaction by facilitating interventional procedures and minimizing patient suffering.

POTENTIAL HARMS

Because individual patients vary in their response to medications, and sedation for analgesia is a continuum, the practitioner providing sedation and analgesia needs to be proficient in airway management and cardiovascular support, and possess the skills required to rescue a patient from one level greater than the intended level of sedation

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Recommendations offered in this policy are not intended to represent the only diagnostic and management options that the emergency physician should consider. American College of Emergency Physicians (ACEP) clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.
- There remains a relative lack of high-quality data in some areas of procedural sedation. It must be carefully noted, however, that despite the statements made in this policy, individual institutions will still be accredited on the basis of the criteria of the respective accrediting organization, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Feb

GUIDELINE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Emergency Physicians

GUIDELINE COMMITTEE

Clinical Policies Subcommittee on Procedural Sedation and Analgesia

ACEP Clinical Policies Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians Web site.

Print copies: Available from the American College of Emergency Physicians, ACEP Customer Service Department, P.O. Box 619911, Dallas, TX 75261-9911, or call toll free: (800) 798-1822, touch 6.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 24, 2005. The information was verified by the guideline developer on March 28, 2005.

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